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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,888	05/31/2005	Thomas R. Young	63-000210US	1367

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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

KALLIS, RUSSELL

ART UNIT	PAPER NUMBER
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1638

MAIL DATE	DELIVERY MODE
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12/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,888	Applicant(s) YOUNG ET AL.	
	Examiner RUSSELL KALLIS	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,7-9,15,16,31-33,39,43,66,69,70,77 and 97-106 is/are pending in the application.
- 4a) Of the above claim(s) 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,8,9,15,16,31-33,39,43,66,69,70,77 and 97-106 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 2, 7-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77 and 97-106 are pending. Claim 7 is withdrawn. Claims 1-2, 8-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77, and 97-106 are examined.

Rejection of claims 1, 9, 39, 43, 66, 69, 77, 97, 98, 101 and 104 under 35 U.S.C. 102(e) and 102(b) is withdrawn in view of Applicants' amendments.

Rejection of claims 1-2, 8-9, 39, 43, 66, 69-70, 77, 97, 98, 101 and 104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 5,952,543 is withdrawn in view of Applicants' amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claims 1-2, 8-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77, and 97-106 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/16/2008. Applicant's arguments filed 8/18/2008 have been considered but are not deemed persuasive.

Applicant asserts that the Fraser and Ye references are examples of how phytoene synthase sequences control carotenoid biosynthesis in transformed plants is misplaced because those experiments were directed to expressing, in sense orientation, phytoene synthase genes in order to express a phytoene synthase polypeptide so that there would be an increase in carotenoid

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content in transformed plant tissue. In those experiments there is no requirement for an interaction at the RNA level that would require substantial sequence homology or sequence identity as in the instant claims that are drawn to decreases in the accumulation of carotenoids. Further with respect to Applicants' remarks directed to the Xe reference, the expression of phytoene synthase alone will not result in colored rice seeds because phytoene, which is synthesized by phytoene synthase is colorless. The Xe reference teaches that in order to synthesize beta-carotene in rice an additional bacterial phytoene desaturase, which possess four activities, was required or only an additional lycopene beta-cyclase.

Applicant further asserts that phytoene synthases exhibit 80% sequence identity at the amino acid level across plant species and this relationship is sufficient for easy identification of a phytoene synthase (response page 14).

Applicant has presented no evidence of the percent identity relationship and more importantly as noted in the previous office action, a sequence from within a species having 85% identity relationship (albeit at the nucleotide level that would encompass any polynucleotide encoding a polypeptide having 80% identity at the amino acid level) were shown not to function in antisense repression of carotenoid biosynthesis. For example, tomato transformed with the PSY1 gene encoding an isoform of the tomato phytoene synthase when expressed constitutively using the CaMV promoter had no effect upon the PSY2 isoform of the gene which is expressed primarily in non flowering tissue (Bird C. *et al.* Bio/Technology, July 1991 Vol. 9, No. 7, pp. 635-639; see page 636 in column 1 1st paragraph of Results section). This is made evident in the amount of carotenoids that were produced in the various plant tissues. In fruits and flowers where the PSY1 isoform is expressed there was significant reduction in the amount of various

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carotenoids when compared to non-transformed plants. In tissues where PSY2 is expressed, such as leaves, there was no effect upon the level of carotenoids when compared to non-transformed plants (Bramley P. *et al.* The Plant Journal; 1992, Vol. 2 No. 3, pp. 343-349; see Table 4 for comparison of flower and leaf). Further, the sequence identity relationship between the two isoforms shows that there is 85% sequence conservation at the polynucleotide level in the coding regions between PSY1 and PSY2 (Bartley *et al.* The Journal of Biological Chemistry; 5 December 1993, Vol. 268. No. 34 pp. 25718-25721; see page 25721 in column 1 lines 11-14);.

Since the specification does not teach the relationship between the endogenous phytoene synthase sequences of pineapple and the heterologous sequences taught in the art to the extent that one of skill in the art would recognize a phytoene synthase sequence that would result in a reduction of carotenoid. Finally, Applicants' specification does not teach the endogenous sequences of pineapple and since it is not clear which of the heterologous sequences taught in the art would yield a reduction of carotenoid when transformed into pineapple, Applicant has not described the broadly claimed genus of carotenoid biosynthetic polypeptide expression regulators that control carotenoid accumulation.

Claims 1-2, 8-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77, and 97-106 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 5/16/2008. Applicant's arguments filed 8/18/2008 have been considered but are not deemed persuasive.

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Applicant asserts that there are examples cited that teach control of, or modulation of carotenoid accumulation (response page 15). However none of those recited teach antisense reduction or any other type of reduction in expression using a non-identical heterologous polynucleotide (see arguments *supra*).

Applicant asserts that sequences can be optimized recombinantly (response page 15). This would not be possible because Applicants have not taught the endogenous pineapple sequences and thus it is not known toward what particular sequence identity or conserved sequence identities those sequence should be optimized. Applicants' assertion that transformation would allow for selection based upon color change is not persuasive because there is considerable unpredictability that would lead to undue trial and error experimentation in transforming with a myriad of sequences in a multitude of plants to find a heterologous sequence that when expressed would reduce carotenoid accumulation.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue trial and error experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

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Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 8-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77, and 97-106 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 10, 17, 18, 21-23 of copending Application No. 10/536,885. Although the conflicting claims are not identical, they are not patentably distinct from each other because both pending claim sets are drawn to transformation of non-apical meristematic cells pineapple with carotenoid biosynthetic genes that are obvious over each other.

The Examiner acknowledges Applicants' intent to file a terminal disclaimer upon a finding of allowable subject matter.

Claims 1-2, 8-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77, and 97-106 remain rejected.

Claims 1-2, 8-9, 15, 16, 31-33, 39, 43, 66, 69, 70, 77, and 97-106 are deemed free of the prior art given the failure of the prior art to teach or reasonably suggest a method of transforming pineapple using organogenetically cultured cells and polynucleotides encoding carotenoid biosynthetic polypeptides to decrease accumulation of carotenoids.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to RUSSELL KALLIS whose telephone number is (571)272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Russell Kallis/
Primary Examiner, Art Unit 1638
December 2, 2008

Application Number 	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/536,888	YOUNG ET AL.	
	Examiner	Art Unit	
	RUSSELL KALLIS	1638	